510(K) SUMMARY

(Per requirements of 21 CFR 807.92.)

JUN 0 3 2014

The Assigned 510(k) number is: K132557

1. **Applicant's Identification:**
   JIAMEI-UN CO., LTD
   5F., No.79, Sec. 1, Nankan Rd., Luzhu Township, Taoyuan County 338, Taiwan (R.O.C.)

   Correspondence:
   Yu-Hong Chen
   Chief Executive Officer
   Office Telephone:+886-3-2125437
   Office Fax: +886-3-212-6140
   Email: ewnl88@yahoo.com.tw

   Date of submission: July 15th, 2013
   Date of resubmission: February 17, 2014
   Date of updated contact information: April 20, 2014

2. **Device name:**
   Proprietary name: EWNL™ Safety Syringe with Needle

   Regulatory information:
   A. Regulation section: 21CFR880.5860
   B. Classification: Class II
   C. Product Code: FMI/MEG
   D. Common name: Piston syringe
   E. Panel: General Hospital

3. **Predicate device:**
   - DuoPro™ Safety Syringe, 3mL, 5mL (DuoProSS™) (K022806)
   - Bak'Snap DuProSS™ Retractable Safety Syringe, 10 mL(K034031)

4. **Intended Use:**
   EWNL™ Safety Syringe with Needle (1mL, 2 mL, 3 mL, 5 mL, and 10 mL) is a sterile, single-use, disposable and non-reusable manual retractable safety syringe, intended for medical purposes for injection of fluids into the body, while reducing the risks of sharps injuries and the potential for syringe reuse. This syringe is intended to be used by nurse, clinicians, or professional healthcare providers only.

5. **Device Description & Technological characteristics:**
   EWNL™ Safety Syringe with Needle is a sterile, single-use, disposable, non-reusable, manual retractable safety syringe provided with needle. EWNL™ Safety Syringe is intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. The device is intended for injection of fluids into, or withdrawal from, the body. The function of EWNL™ Safety Syringe works the same as a conventional hypodermic syringe except for its

ability to retract the contaminated needle inside the syringe barrel after the injection. Needle retraction is activated manually by the syringe user. The device also features a destructible plunger, which can be pulled back, snapped off, and the entire unit disposed of after the needle is locked inside the syringe barrel. With this sharps injury prevention design, the syringe user is protected from accidental needle sticks.

EWNL™ Safety Syringe is compatible with any other hypodermic single lumen needle which has the female luer connector (hub). The EWNL™ Safety Syringe and the two predicate devices DuoPro™ Safety Syringes are all provided sterile, single-use, and disposable. Similar to its predicate devices (see Section 6 below), tthe needle is retracted manually and enclosed within the syringe barrel once the injection has been completed. Once the plunger is fully pulled back, the needle is locked inside the syringe barrel and the plunger rod can be snapped off. Based on this device design and its operating principles, the device is rendered non-reusable and disposable.

6. **Substantial Equivalence:**

The EWNL™ Safety Syringe with Needle is substantially equivalent to the cited predicate devices (i.e., DuoPro™ Safety Syringe, 3mL, 5mL, cleared under K022806 & Bak'Snap DuProSS™ Retractable Safety Syringe, 10 mL, cleared under K034031). This is based on the similarities in the intended use, operating principle, device design and technological characteristics.

The operating principles and device design for EWNL™ Safety Syringe is substantially equivalent to the predicate devices (K022806 and K034031).

The proposed EWNL™ Safety Syringe is the same as the predicate devices indicated for injecting fluids into the body while helping to reduce the risks of sharps injuries.

The proposed EWNL™ Safety Syringe is the same as the predicate devices that have an annulus connector that holds the hypodermic needle and to be mated with the projection spike on the piston, thereby locking the needle to the plunger. These three syringes require the user to manually retract the needle plunger into the syringe barrel, break off the plunger rod, and discard the pieces.

The EWNL™ Safety Syringe is provided with a single lumen hypodermic needle whereas the two predicate devices DuoPro™ Safety Syringes can be ordered with or without a needle.

The modified EWNL™ Safety Syringe uses a luer lock connector, while the predicate devices DuoPro™ Safety Syringe use either a luer slip or luer lock needle connector.

The major difference between the modified EWNLTM Safety Syringe (1mL, 2 mL, 3 mL, 5 mL, and 10 mL) and the predicate devices DuoPro™ Safety Syringe (3 mL, 5mL) and Bak'Snap DuProSS™ Retractable Safety Syringe (10 mL) is the syringe volume (and associated dimensions). This difference does not affect the performance of the syringe, since syringe size is typically determined by drug volume to be administered and user preference.

JIAMEI-UN CO., LTD believes that the differences between the EWNL™ Safety Syringe with Needle and the cited predicate devices do not affect the performance or raise new issues of safety and effectiveness.

7. **Performance Summary:**
EWNL™ Safety Syringe with Needle is substantially equivalent and meets the same acceptance criteria as the predicate devices in K022806 and K034031. In terms of physical specification, chemical specification, biocompatibility, and sterilization of the proposed device conforms to applicable standards including ISO 7864, ISO 594, ISO 7886-1, ISO 10993 series, ISO 11135-1, and FDA Guidance. The simulated clinical test results indicate no sharps injuries or failures of the safety mechanism occurred. These results support the claim that *EWNL*™ Safety Syringes may reduce the risk of accidental needlestick injuries. The positive responses from the study participants regarding functional performance aspects also support the functionality as per the device design and its operating principle.

8. **Conclusion:**
EWNL™ Safety Syringe with Needle in this 510(k) submission is substantially equivalent to the predicate devices (K022806 and K034031) in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 3, 2014

JIAMEI-UN COMPANY LIMITED
Mr. Yu-Hong Chen
Chief Executive Officer
5F., No.79, Sec. 1. Nankan Rd., Luzhu Township,
Taoyuan County 338, TAIWAN (R.O.C.)

Re: K132557
Trade/Device Name: EWNL™ Safety Syringe with Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMI/MEG
Dated: February 21, 2014
Received: March 5, 2014

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132557

Device Name

EWNL Safety Syringe with Needle

Indications for Use *(Describe)*

EWNLTM Safety Syringe with Needle (1mL, 2mL, 3mL, 5mL, and 10mL) is a sterile, single-use, disposable and non-reusable manual retractable safety syringe, intended for medical purposes for injection of fluids into the body, while reducing the risks of sharps injuries and the potential for syringe reuse. This syringe is intended to be used by nurse, clinicians, or professional healthcare providers only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman -S
Date: 2014.06.03 12:04:05 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."